106TH CONGRESS
1ST SESSION

S. 1626

To amend title XVIII of the Social Security Act to improve the process by which the Secretary of Health and Human Services makes coverage determinations for items and services furnished under the medicare program, and for other purposes.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 23 (legislative day, SEPTEMBER 22), 1999

Mr. HATCH (for himself, Mr. NICKLES, Mr. BREAUX, Mr. GRASSLEY, Mr. MURKOWSKI, and Mr. BAYH) introduced the following bill; which was read twice and referred to the Committee on Finance

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A BILL

To amend title XVIII of the Social Security Act to improve the process by which the Secretary of Health and Human Services makes coverage determinations for items and services furnished under the medicare program, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Medicare Patient Access to Technology Act of 1999".

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

SEC. 2. FINDINGS.

Congress finds the following:

(1) In order to ensure genuine access of medicare beneficiaries to medical technologies, the Secretary of Health and Human Services has an obligation to integrate and coordinate its medical technology coverage policy determination process with agency policies and practices that govern assignment of procedure codes, establishment and adjustment of payment levels and groupings, and issuance of timely instructions to contractors.

(2) The effectiveness of the medicare program in meeting beneficiary needs is compromised if access to state-of-the-art medical care is denied as a result of ineffective agency performance in the coverage, coding, or payment processes; or in the ineffective administrative execution of medical technology decisions.

(3) The Secretary of Health and Human Services owes medicare beneficiaries the assurance that the various medicare payment systems (in both the

fee-for-service and managed care areas) are operated in a way that reflects developments in, and improvements upon, medical technology by properly setting and adjusting payment levels and payment groups.

(4) Clear, predictable, and well-functioning coverage, coding, and payment systems are particularly critical to this Nation's small medical technology companies, which are the originators of most medical product innovations.

(5) Unless the administrators of the coverage, coding, and payment systems under the medicare program review products promptly, apply standards appropriate for medical technology, and provide reasonable reimbursement levels, small medical technology companies will experience difficulties in bringing the benefits of medical innovation to medicare beneficiaries.

(6) By creating an internal task force to examine methods for integrating coverage, coding, and payment decisions, the Secretary of Health and Human Services has taken an important first step toward preserving innovation, and should continue to work to bring these 3 processes together.

SEC. 3. ESTABLISHMENT OF MEDICARE ACCESS TO TECHNOLOGY ADVISORY COMMITTEE.

(a) IN GENERAL.—Title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) is amended by adding at the end the following:

"MEDICARE ACCESS TO TECHNOLOGY ADVISORY COMMITTEE

"SEC. 1897. (a) MEDICARE ACCESS TO TECHNOLOGY ADVISORY COMMITTEE.—

"(1) ESTABLISHMENT.—

"(A) IN GENERAL.—Not later than July 1, 2001, the Secretary shall establish the Medicare Access to Technology Advisory Committee (in this subsection referred to as the 'Committee') under section 9(a)(1) of the Federal Advisory Committee Act for the purpose of securing advice and recommendations on issues related to coverage, payment, and coding decisions.

"(B) CONSULTATION.—The Secretary shall consult with the Committee, and may consult directly with any panel of the Committee established under subsection (b)(1).

"(2) DUTIES.—The Committee, and the panels of the Committee, shall provide advice and recommendations to the Secretary with respect to—

"(A) the issues referred to the Medicare Coverage Advisory Committee (established by the Secretary on November 24, 1998, notice of which was published in the Federal Register on December 14, 1998 (63 Fed. Reg. 68780));

"(B) policies regarding payment issues and policies regarding coding issues under this title, including identification of—

"(i) policies and mechanisms to help ensure that payment and coding decisions are made—

"(I) in a way that encourages access to high-quality medical care under this title;

"(II) through processes that allow for significant public participation; and

"(III) expeditiously, in accordance with specified timeframes for each significant step in the process of making such decisions;

"(ii) an equitable mechanism for determining fee schedule payment amounts for items and services, except for physi-

cians' services (as defined in section 1861(q)); and

"(iii) processes for reconsideration and appeal of determinations of fee schedule payment amounts; and

"(C) the integration of policies on coverage, payment, and coding under this title into a process that ensures timely access to high-quality medical care.

"(3) POLICIES REGARDING CODING ISSUES.—

"(A) For purposes of paragraph (2)(B), policies regarding coding issues include any policy resulting from an action described in clause (i) of subparagraph (B).

"(B)(i) An action described in this clause is the action of any person to create, revise, update, modify, adopt, edit, abridge, or otherwise affect the form of a code used by the Secretary in the operation of the program under this title.

"(ii) As used in clause (i), the term 'code' means any code included in level I or II of the Health Care Financing Administration Common Procedure Coding System.

"(4) DURATION.—Section 14(a)(2)(B) of the Federal Advisory Committee Act shall not apply to the Committee.

"(b) COMMITTEE PROCEDURES.—In administering the Committee under this section, the Secretary shall—

"(1) organize the Committee into panels of experts;

"(2) ensure participation on the Committee of individuals who—

"(A) are experts in a variety of medical specialties and fields of science, including—

"(i) specific areas of medical technology, including suppliers and manufacturers of clinical and diagnostic testing supplies and durable medical equipment;

"(ii) medical research generally, including experts in the study of treatment outcomes; and

"(iii) other areas relevant to the duties assigned to the Committee (taking into account, as appropriate, any affiliations individuals may have with organizations possessing information, expertise, and other resources that would contribute signifi-

cantly to the work of the Committee and its panels);

"(B) are qualified by training and experience to evaluate the matters referred to the Committee, including a representative of consumer interests and a representative of the interests of manufacturers of medical technology on each panel; and

"(C) have adequately diversified backgrounds so that the Committee will provide balanced advice and recommendations;

"(3) permit each panel to independently advise the Secretary with regard to matters referred to the panel, without the need to obtain the concurrence of the full Committee;

"(4) provide for—

"(A) full public participation, to the extent required or permitted under law, in any meeting of the Committee or its panels;

"(B) publication of notice of any such meeting on the official Internet site of the Department of Health and Human Services at least 60 days before such meeting, including—

"(i) a statement of the issues to be considered by the Committee or panel;

"(ii) a description of the specific information that is relevant to such issues; and

"(iii) the text of any proposals the Secretary will ask the Committee or panel to consider;

"(C) consideration by the Committee or panel of relevant information or testimony that is submitted by the public;

"(D) public access in a central repository to the information described in subparagraph (C) at least 20 days before the meeting; and

"(E) the panels to meet at least once every 3 months unless there is no business to conduct;

"(5) require the Committee and its panels to provide, with any recommendation, a summary of the reasons for the recommendation and a summary of the data upon which the recommendation is based; and

"(6) make a verbatim transcript of each Committee and panel proceeding (other than those portions that are closed to the public in accordance with law) available to the public within 14 days on the of-

ficial Internet site of the Department of Health and Human Services.".

(b) TRANSITION, CONTINUING RESPONSIBILITY FOR UNFINISHED DUTIES.—

(1) IN GENERAL.—Effective on the date the Medicare Access to Technology Advisory Committee is established, the Secretary of Health and Human Services shall provide for the transfer to such committee of any assets and staff of the Medicare Coverage Advisory Committee, without any loss of benefits or seniority by virtue of such transfers.

(2) AVAILABILITY OF FUNDS.—Fund balances available to the Medicare Coverage Advisory Committee for any period shall be available to the Medicare Access to Technology Advisory Committee for such period for like purposes.

(c) REPORTING REQUIREMENTS.—

(1) Not later than December 1 of each year, beginning with 2000, the Secretary of Health and Human Services shall submit to Congress a report describing the timeliness of the Secretary's national coverage policy decisionmaking during the preceding fiscal year measured by the timeframes the Secretary has published for the national coverage policy determination process, and such report shall include

the actual time periods that were necessary to complete and fully implement national coverage policy determinations and each significant step in the process.

(2) Not later than July 1, 2000, the Secretary of Health and Human Services shall submit to Congress a report, on the nature of the coverage policy determination processes used by Medicare+Choice organizations established under part C of title XVIII of the Social Security Act (42 U.S.C. 1395w–21 et seq.), including a detailed explanation of any steps taken to ensure that the coverage policy determination processes under the Medicare+Choice program established under such part—

(A) produce results consistent with the coverage policy determinations reached under parts A and B of such title (42 U.S.C. 1395 et seq.); and

(B) treat any medical device being investigated under section 520(g) of the Federal Food, Drug, and Cosmetic Act (42 U.S.C. 360j(g)), in a manner consistent with the treatment afforded such medical device under parts A and B of the Social Security Act (42 U.S.C. 1395 et seq.).

SEC. 4. ANNUAL ADJUSTMENTS TO MEDICARE PAYMENT SYSTEMS FOR CHANGES IN TECHNOLOGY AND MEDICAL PRACTICE.

(a) IN GENERAL.—Title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) is amended by inserting after section 1888 the following:

"ANNUAL ADJUSTMENTS TO MEDICARE PAYMENT SYSTEMS FOR CHANGES IN TECHNOLOGY AND MEDICAL PRACTICE

"SEC. 1889. (a) IN GENERAL.—Notwithstanding any other provision of this title, the Secretary shall adjust the appropriate elements of the payment systems established under sections 1833(i)(2)(A), 1833(t), 1848, and 1886(d) (including relative payment weights, relative value units, weighting factors, classifications, and case assignments) at least annually to ensure that payments, classifications, and assignments under such systems—

"(1) appropriately reflect changes in medical technology and medical practice affecting the items and services for which payment may be made under such systems; and

"(2) promote the efficient and effective delivery of high-quality health care.

"(b) RULES FOR DETERMINING ADJUSTMENTS.—Except as provided in subsection (c), the provisions of sections 1833(i)(2)(A), 1833(t)(7), 1848(c)(2)(B), and

1886(d)(4)(C) shall apply to the annual adjustments required by this section in the same manner and to the same extent as they apply to the adjustments of relative payment weights, relative value units, weighting factors, classification, and assignments, respectively, that are authorized or required by such sections.

"(c) USE OF INTERNAL DATA COLLECTED BY THE SECRETARY.—

"(1) IN GENERAL.—In determining the adjustments required by this section, the Secretary may not—

"(A) decline to make an adjustment that is based on data collected by the Secretary in the administration of the program established under this title if the data reflect a representative sample of cases that is statistically valid; and

"(B) establish a uniform period of time (such as 1 year) from which such data must be drawn.

"(2) DEADLINE FOR SUPPLYING INTERNAL DATA.—

"(A) IN GENERAL.—Subject to subparagraph (B), the Secretary shall establish a reasonable deadline for the submission of data col-

lected by the Secretary to be used in making the adjustments required by this section.

"(B) LIMITATION.—In no event may the deadline established under subparagraph (A) be more than 7 months before the first day of the provider payment update period for which the adjustment or adjustments to which the data relates would be effective.

"(d) USE OF EXTERNAL DATA.—

"(1) IN GENERAL.—Subject to paragraph (2), in determining the adjustments required by this section, the Secretary shall utilize data other than data collected by the Secretary in the administration of the program established under this title if—

"(A) data collected by the Secretary in the administration of such program are not available at the time such adjustments are being determined; and

"(B) such other data are reliable and verifiable.

"(2) EXTERNAL DATA FACILITATING THE USE OF INTERNAL DATA.—In determining the adjustments required by this section, the Secretary may not—

"(A) decline to use data other than data collected by the Secretary if such other data—

"(i) enable the Secretary to identify or refine data collected by the Secretary for use in making such an adjustment; and

"(ii) are based on a representative sample of cases that is statistically valid; or

"(B) establish a uniform period of time (such as 1 year) from which such data must be drawn.

"(3) ALTERNATIVE SOURCES OF DATA.—In determining the adjustments required by this section, the Secretary shall use data, that otherwise meets the requirements of this subsection, collected by (or on behalf of)—

"(A) private payers;

"(B) manufacturers of medical technologies;

"(C) suppliers;

"(D) groups representing physicians and other health care professionals;

"(E) groups representing providers;

"(F) clinical trials; and

"(G) such other sources as the Secretary determines to be appropriate.

"(4) CLARIFICATION.—Nothing in this title shall be construed as—

"(A) requiring the Secretary to identify all claims submitted under a payment system established under section 1833(i)(2)(A), 1833(t), 1848, or 1886(d), involving the use of a medical technology before the Secretary may make the adjustments under this section (or under section 1833(i)(2)(A), 1833(t), 1848, or 1886(d)) with respect to such technology; or

"(B) authorizing the Secretary to defer action on such an adjustment until all such claims are identifiable.

"(5) DEADLINE FOR SUPPLYING EXTERNAL DATA.—The Secretary shall establish a reasonable deadline for the submission of data other than data collected by the Secretary to be used in making the adjustments required by this section. In no event may the deadline established under this paragraph be more than 9 months before the first day of the provider payment update period for which the adjustment or adjustments to which the data relates would be effective.

"(e) TIMING OF ADJUSTMENTS.—

"(1) IN GENERAL.—The annual adjustments required by this section shall—

"(A) apply to provider payment update periods beginning on or after October 1, 2000; and

"(B) be described in the proposed and final rules published by the Secretary with respect to changes to a payment system established under section 1833(i)(2)(A), 1833(t), 1848, or 1886(d), for the provider payment update period to which they relate, together with a description of the data on which such adjustments are based.

"(2) PROVIDER PAYMENT UPDATE PERIOD DEFINED.—For purposes of this section, the term 'provider payment update period' means—

"(A) in the case of the payment systems established under sections 1833(t) and 1848, a calendar year; and

"(B) in the case of the payment systems established under sections 1833(i)(2)(A) and 1886(d), a fiscal year beginning on October 1.".

(b) CONFORMING AMENDMENTS.—

(1) AMBULATORY SURGICAL CENTERS.—Section 1833(i)(2)(A) of the Social Security Act (42 U.S.C. 1395l(i)(2)(A)) is amended by striking "Each" in the second sentence and inserting "Subject to section 1889, each".

(2) OUTPATIENT HOSPITAL PROSPECTIVE PAYMENT SYSTEM.—Section 1833(t)(6)(A) of such Act (42 U.S.C. 1395l(t)(6)(A)) is amended by striking "The" and inserting "Subject to section 1889, the".

(3) PHYSICIAN PAYMENT.—Section 1848(c)(2)(B)(i) of such Act (42 U.S.C. 1395w–4(c)(2)(B)(i)) is amended by striking "The" and inserting "Subject to section 1889, the".

(4) INPATIENT HOSPITAL PROSPECTIVE PAYMENT SYSTEM.—Section 1886(d)(4)(C)(i) of such Act (42 U.S.C. 1395ww(d)(4)(C)(i)) is amended by striking "The" and inserting "Subject to section 1889, the".

SEC. 5. TREATMENT OF NEW MEDICAL TECHNOLOGIES UNDER MEDICARE OPD PPS.

(a) TEMPORARY EXCLUSION OF CERTAIN MEDICAL TECHNOLOGIES.—

(1) IN GENERAL.—Section 1833(t)(1) of the Social Security Act (42 U.S.C. 1395l(t)(1)) is amended—

(A) in subparagraph (B)(iii)—

(i) by inserting "(I)" after "include";

(ii) by striking "or ambulance services" and inserting ", (II) ambulance services"; and

(iii) by striking "1834(l)." and inserting "1834(l), or (III) for the time period specified in clause (ii) of subparagraph (C), the medical technologies described in clause (i) of such subparagraph, except that this subclause shall not be construed to constitute the sole basis on which any such medical technologies may be excluded from the payment system established under this subsection."; and

(B) by adding at the end the following:

"(C) MEDICAL TECHNOLOGIES SUBJECT TO TEMPORARY EXCLUSION.—

"(i) MEDICAL TECHNOLOGIES DESCRIBED.—Subject to clause (v), the medical technologies described in this clause are the following:

"(I) Any medical technology that was reimbursed as a hospital outpatient service under this part during

1996 for which sufficient, reliable, and verifiable data drawn from such year is not available.

"(II) Any medical technology that was not reimbursed as a hospital outpatient service under this part during 1996 but was reimbursed as such a service as of the day before the date on which the system established under this subsection first took effect.

"(III) Subject to clause (iv), any medical technology that was not reimbursed as a hospital outpatient service under this part as of the day before such system took effect but that is payable as such a service on or after the date on which such system first took effect.

"(IV) Drugs or biological products used as treatment or supportive care for patients with cancer, including chemotherapeutic agents, antiemetics, hematopoietic growth factors, colony stimulating factors, and biological response modifiers.

"(V) Drugs or biological products designated as a drug for a rare disease or condition under section 526 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360bb) and approved or licensed for introduction into interstate commerce by the Commissioner of Food and Drugs.

"(VI) Drugs or biological products used for the treatment of end-stage renal disease not included in the composite rate under section 1881 and for which a payment methodology is not specifically established by this Act, other than by section 1842(o).

"(VII) Radiopharmaceutical drugs or biological products used in diagnostic, monitoring, and therapeutic nuclear medicine procedures.

"(VIII)(aa) Blood components and blood products, including any such component or product derived from plasma fractionation or biotechnology analog of such component or product; and

"(bb) Any medical technology or service used in connection with blood transfusion, blood product exchange, or other blood-related therapy, including plasmapheresis, photopheresis, hematopoietic stem cell collection or replacement therapy.

"(IX) Drugs or biological products with respect to which the mean cost for a dose exceeds the otherwise applicable fee schedule amount under the system established under this subsection by 2 standard deviations from such mean.

"(ii) TIME PERIOD SPECIFIED.—Subject to clause (iii), the time periods specified in this clause are not less than—

"(I) for a medical technology described in subclause (I) or (II) of clause (i), the period that begins with the date on which the system established under this subsection first takes effect and ends with (and includes) the last day of the fourth calendar

year to begin on or after such date; and

"(II) for a medical technology described in subclause (III) of clause (i), the period that begins with the date on which a claim is first submitted under this part with respect to such technology and ends with (and includes) the last day of the fourth calendar year to begin on or after such date.

"(iii) PROCESS FOR INCLUSION OF EXCLUDED MEDICAL TECHNOLOGIES.—No medical technology excluded under clause (i) may be designated as a covered OPD service unless the Secretary completes the following steps:

"(I) The Secretary shall assign a unique code to the medical technology to be designated as a covered OPD service.

"(II) The Secretary shall issue instructions for using any code assigned under subclause (I) and document the usage of the medical tech-

nology to which the code is assigned in the hospital outpatient department.

"(III) The Secretary shall require hospitals to use the codes assigned under subclause (I) for not less than 2 years.

"(IV) The Secretary shall obtain sufficient, reliable, and verifiable cost and utilization data from a representative group of hospitals that use the medical technology, including hospitals of different sizes, geographic locations, degrees of specialization, case-mix, and the dependence of the hospitals on funds provided under the medicare program under this title and the medicaid program under title XIX.

"(V) The Secretary, based on the data obtained under subclause (IV), shall develop a proposed OPD service classification for the medical technology, paying particular attention to the potential of the proposed classification to create economic incentives

that could reduce patient access to the medical technology.

"(VI) The Secretary shall publish in the Federal Register a proposed rule regarding the classification described under subclause (V) and supporting cost and utilization data.

"(VII) The Secretary shall provide for a comment period of not less than 90 days, beginning on the date on which the Secretary publishes the proposed rule and supporting data described in subclause (V).

"(iv) NEW TECHNOLOGIES DESCRIBED.—As of the effective date of this clause, the technologies to which clause (i)(III) applies include—

"(I) existing technologies not previously reimbursed as hospital outpatient services;

"(II) newly developed technologies approved or licensed for introduction into interstate commerce by the Commissioner of Food and Drugs after December 31, 1995; and

"(III) new applications of existing technologies.

"(v) LOW-COST MEDICAL TECHNOLOGIES.—The medical technologies described in clause (i) do not include any medical technology if the cost of such technology is insignificant in relation to the OPD fee schedule amount (as calculated under paragraph (3)(D)) payable for the service (or group of services).

"(vi) MEDICAL TECHNOLOGY DEFINED.—For purposes of this subsection, the term 'medical technology' means any discrete and identifiable regimen or modality used to diagnose or treat illness, prevent disease, maintain patient well-being, or facilitate the provision of health care services.

"(D) TREATMENT OF IMPLANTABLE DEVICES.—

"(i) PAYMENT BASIS DURING AND AFTER EXCLUSION PERIOD.—If a medical technology that is an implantable device is excluded from the payment system estab-

lished under this subsection pursuant to subparagraph (B)(iii)(III), such device—

"(I) shall be paid on the basis described in subsection (a)(2)(B)(i) during the period of such exclusion; and

"(II) shall be paid for under the system established under this subsection during the period following such exclusion (and not under a fee schedule established under subsection (a) or (h) of section 1834).

"(ii) PAYMENT BASIS FOR DEVICES WITH NO EXCLUSION PERIOD.—If a medical technology that is an implantable device was not excluded from the payment system established under this subsection pursuant to subparagraph (B)(iii)(III)—

"(I) such device shall be included in such system (and not a fee schedule established under subsection (a) or (h) of section 1834); and

"(II) in determining the relative payment weights (described in paragraph (2)(C)) for the service or group

of services within which such device is classified under such system, the Secretary shall meet the requirements of clause (iii).

"(iii) DETERMINATION OF RELATIVE PAYMENT WEIGHTS.—Subject to paragraph (11), in determining the relative payment weights described in clause (ii)(II) for an implantable device, the Secretary—

"(I) may not substitute data on the amount that would be paid for such device under a fee schedule established under subsection (a) or (h) of section 1843 for data on the amounts paid for such device under subsection (a)(2)(B)(i); and

"(II) shall rely solely on data on the amounts paid for such item or service under such subsection (a)(2)(B)(i).".

(2) ADMINISTRATIVE AND JUDICIAL REVIEW.—Section 1833(t)(9) of the Social Security Act (42 U.S.C. 1395l(t)(9)) is amended—

(A) by striking "LIMITATION ON REVIEW.—There" and inserting "LIMITATION ON REVIEW.—

"(A) IN GENERAL.—Subject to subparagraph (B), there"; and

(B) by adding at the end the following:

"(B) RULE OF CONSTRUCTION.—This paragraph shall not be construed as limiting administrative or judicial review of determinations of whether a medical technology is required to be excluded from the payment system established under this subsection pursuant to paragraph (1)(B)(iii)(III).".

(b) LIMITING VARIATION IN THE COSTS OF SERVICES CLASSIFIED WITHIN THE SAME GROUP.—Section 1833(t)(2) of the Social Security Act (42 U.S.C. 1395l(t)(2)) is amended by adding at the end the following:

"For purposes of subparagraph (B), items and services within a group shall not be treated as 'comparable with respect to the use of resources' if the highest mean cost for an item or service within the group is more than 2 times greater than the lowest mean cost for an item or service within the group.".

(c) ANNUAL REVIEW OF OPD PPS COMPONENTS.—Section 1833(t)(6)(A) of the Social Security Act (42 U.S.C. 1395l(t)(6)(A)) (as amended by section 4(b)(2)) is amended by striking "may periodically review" and inserting "shall review not less than annually".

(d) SPECIAL RULES FOR EXCLUDED SERVICES.—

(1) UNADJUSTED CO-PAYMENT AMOUNT.—Section 1833(t)(3)(B) of the Social Security Act (42 U.S.C 13951(t)(3)(B)) is amended—

(A) in clause (i), by inserting "or to a service excluded under paragraph (1)(C)" after "(or group of such services)";

(B) in clause (ii), by inserting "or excluded service under paragraph (1)(C)" after "furnished in a year"; and

(C) by adding at the end the following:

"(iv) RULES FOR EXCLUDED SERVICES.—The Secretary shall establish rules for the establishment of an unadjusted co-payment amount for medical technologies excluded under paragraph (1)(C)(i) for which no national median of charges is available based on the unadjusted copayment amount for medical technologies with similar average wholesale prices.".

(2) BENEFICIARY COST SHARING.—Section 1833(t) of the Social Security Act (42 U.S.C. 13951(t)) is amended.—

(A) by redesignating paragraphs (6) through (9) (as amended by subsections (a)(2) and (c) and section 4(b)(2)) as paragraphs (7) through (10), respectively; and

(B) by inserting after paragraph (5) the following:

"(6) PAYMENT AMOUNTS FOR EXCLUDED SERVICES—

"(B) COPAYMENT AMOUNT FOR EXCLUDED SERVICES—

"(i) IN GENERAL.—Except as provided in clause (ii), the copayment amount for services excluded under subparagraph (1)(C) shall be the unadjusted copayment amount for such services as determined under paragraph (3)(B).

"(ii) EXCEPTION.—If the copayment amount determined under clause (i) is less than 20 percent of the reasonable cost as determined under subparagraph (A), the copayment amount shall be 20 percent of the reasonable cost as so determined.".

(3) CONFORMING AMENDMENT.—Section 1833(a)(2)(B)(i) is amended by striking "furnished before January 1, 1999,".

(e) PAYMENT.—Section 1833(t) of the Social Security Act (42 U.S.C. 1395l(t)) is amended—

(1) by redesignating paragraph (10) (as redesignated by subsection (d)(2)(A)) as paragraph (12); and

(2) by inserting after paragraph (9) the following:

"(10) PAYMENT DURING AND AFTER EXCLUSION PERIOD.—

"(A) IN GENERAL.—Notwithstanding any other provision of this title, items and services excluded from the system established under this subsection pursuant to paragraph (1)(B)(iii)(III) (other than any implantable devices to which paragraph (1)(D) applies)—

"(i) shall be paid on the basis described in subsection (a)(2)(B)(i) during the period of such exclusion; and

"(ii) shall be paid for under the system established under this subsection during the period following such exclusion.

"(B) DETERMINING RELATIVE PAYMENT WEIGHTS.—Subject to paragraph (11), in determining the relative payment weights (described in paragraph (2)(C)) for the service or group of services within which an item or service is classified pursuant to the payment system established under this subsection, the Secretary—

"(i) may not substitute data on the amount that would be paid for such item or service under a fee schedule established under subsection (a) or (h) of section 1843 for data on the amounts paid for such device under subsection (a)(2)(B)(i); and

"(ii) shall rely solely on data on the amounts paid for such item or service under such subsection (a)(2)(B)(i).

"(11) EXCLUSION OF DATA FOR CERTAIN MEDICAL TECHNOLOGIES.—The Secretary may not utilize data with respect to a device for which an exemption granted under section 520(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)) is in effect—

"(A) in determining whether there is adequate data with respect to the device for pur-

poses of clauses (i)(I) and (iii) of paragraph (1)(C); or

"(B) in determining the relative payment weights for the device pursuant to paragraph (1)(D)(iii) or (10)(B).".

(f) REQUIRED CONSULTATION BEFORE LIMITING COVERAGE BY SITE OF SERVICE.—

(1) IN GENERAL.—Notwithstanding any other provision of law, the Secretary may not implement on or after September 8, 1998, any regulatory guidance of the type described in paragraph (2) until the Secretary has consulted with groups representing hospitals, physicians, beneficiaries under the medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), and manufacturers of medical technologies.

(2) REGULATORY GUIDANCE.—The types of regulatory guidance described in this paragraph are proposed, interim final, and final regulations, manual instructions, statements of policy, and other forms of regulatory guidance that would—

(A) deny coverage or payment for an item or service under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) unless the

item or service is furnished on an inpatient basis; or

(B) deny coverage or payment for an item or service under such title unless the item or service is furnished on an outpatient basis.

(g) BASIS FOR DETERMINING WEIGHTING FACTORS.—Section 1833(t)(2)(C) of the Social Security Act (42 U.S.C. 1395l(t)(2)(C)) is amended by striking "median" and inserting "mean".

(h) BUDGET NEUTRALITY ADJUSTMENT.—The Secretary of Health and Human Services shall make such adjustments to the amounts payable under section 1833(t) of the Social Security Act (42 U.S.C. 1395l(t)) as may be necessary to ensure that there is no increase or decrease in the expenditures under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) as a result of the amendments made by this section.

(i) MONITORING ACCESS TO MEDICAL TECHNOLOGY.—

(1) MONITORING AND ANNUAL REPORTS OF THE SECRETARY.—

(A) MONITORING ACCESS.—The Secretary of Health and Human Services shall monitor the utilization of medical technology in hospital outpatient departments.

(B) ANNUAL REPORTS.—The Secretary of Health and Human Services shall annually submit to Congress a report on the utilization of the medical technology monitored under subparagraph (A) together with an analysis of the extent to which access by beneficiaries under the medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) to new medical technologies is affected by the inclusion or exclusion of such technologies in the payment system established under section 1833(t) of such Act (42 U.S.C. 1395l(t)).

(2) COMMENTS AND REPORTS OF MEDPAC.—

(A) COMMENTS.—The Medicare Payment Advisory Commission established under section 1805 of the Social Security Act (42 U.S.C. 1395b–6) (in this paragraph referred to as "MedPAC") shall submit to the Secretary of Health and Human Services comments on any proposed rule regarding the classification of medical technologies excluded from the prospective payment system established under section 1833 of the Social Security Act (42 U.S.C. 1395l(t)).

(B) ANNUAL REPORTS.—

(i) IN GENERAL.—MedPAC shall annually submit to the appropriate committees of Congress a report on the changes in utilization of and access to medical technologies furnished under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) together with its recommendations for such legislation and administrative actions as it considers appropriate to improve access of beneficiaries under the medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) to appropriate medical technologies.

(ii) CONSULTATION.—In preparing the annual report under clause (i), MedPAC shall convene and consult a panel of experts to evaluate the implications of medical technology utilization patterns for the quality of and access to care of beneficiaries under the medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).

(j) EFFECTIVE DATES.—The amendments made by subsections (a), (b), (c), (d), (e), and (g) take effect as if included in the amendments made by section 4523(a)

of the Balanced Budget Act of 1997 (Public Law 105–33; 111 Stat. 445).

SEC. 6. CLARIFICATION OF STANDARD FOR MEDICARE COVERAGE OF DRUGS AND BIOLOGICALS.

(a) IN GENERAL.—Section 1862(a) of the Social Security Act (42 U.S.C. 1395y(a)) is amended by adding at the end the following: "A drug or biological may not be excluded from coverage under this title by reason of paragraph (1)(A) if the drug or biological has been approved by the Food and Drug Administration and is prescribed for a use that has been approved by the Food and Drug Administration or that is supported by 1 or more citations that are included (or approved for inclusion) in 1 or more of the compendia referred to in section 1861(t)(2)(B)(ii)(I).".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to coverage determinations made on or after the date of enactment of this Act.

SEC. 7. PROCESS FOR MAKING AND IMPLEMENTING CERTAIN CODING MODIFICATIONS.

(a) TIMELY ASSIGNMENT OF CODES.—

(1) IN GENERAL.—Notwithstanding title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), the Secretary of Health and Human Services (in this section referred to as the "Secretary") shall—

(A) accept recommendations for HCPCS level II code modifications from the public throughout the year;

(B) cause determinations on recommendations received during the 3 months immediately preceding the last month of a calendar quarter to be made not later than the first day of the following calendar quarter; and

(C) implement approved modifications to HCPCS level II codes established under title XVIII of the Social Security Act (including the medicare fee schedule database) with respect to the payment system not later than 180 days after the date on which the determination approving a modification was made.

(2) SPECIAL RULE FOR CERTAIN MEDICAL TECHNOLOGIES.—For purposes of subparagraph (C), any modification to a HCPCS level II code that is implemented with respect to the payment systems established under title XVIII of the Social Security Act (including the medicare fee schedule database) and that relates to a medical technology described in section 1833(t)(1)(C)(i) of such Act shall be in effect only for—

(A) the purpose of permitting data to be collected with respect to such technology on the basis described in paragraph (1)(D)(i) or (10)(A)(i) (as amended by this Act) of section 1833(t) of such Act; and

(B) the period for which such technology is excluded from such system pursuant to paragraph (1)(B)(iii)(III) of such section.

(b) ELIMINATION OF MARKETING EXPERIENCE REQUIREMENT.—Notwithstanding any provision of title XVIII of the Social Security Act, the Secretary may not require a minimum period of marketing experience with respect to a drug or device as a condition of consideration or approval of a recommendation for a HCPCS level II code modification for such drug or device.

(c) HCPCS LEVEL II CODE MODIFICATION DEFINED.—For purposes of this section, the term "HCPCS level II code modification" means an addition, deletion, or change to the alpha-numeric codes for items not included in level I or level III of the Health Care Financing Administration Common Procedure Coding System (HCPCS).

(d) REPORT.—

(1) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Sec-

retary of Health and Human Services shall submit to Congress a report on the feasibility and desirability of opening meetings of the Alpha-Numeric Editorial Panel of the Department of Health and Human Services to the public.

(2) REASONS FOR DETERMINATION.—If the Secretary determines that opening such meetings to the public is not feasible or desirable, the Secretary shall include in the report a detailed explanation of the reasons for such determination.

(e) EFFECTIVE DATE.—This section takes effect on January 1, 2000.

SEC. 8. RETENTION OF HCPCS LEVEL III CODES.

(a) IN GENERAL.—The Secretary of Health and Human Services shall maintain and continue the use of HCPCS level III codes (as in effect on June 1, 1999), and shall make such codes available to the public.

(b) HCPCS LEVEL III CODES DEFINED.—For purposes of this section, the term "HCPCS level III codes" means the alpha-numeric codes for local use under the Health Care Financing Administration Common Procedure Coding System (HCPCS).

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